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**Dolan**

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(54) **PROSTHETIC VALVE DELIVERY SYSTEM**

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**A61F 2/24** (2006.01)

(52) **U.S. Cl.** ..... **623/2.11**

(58) **Field of Classification Search** ..... 623/2.1–2.19,  
623/1.1–1.12, 1.15–2.1, 1.23, 900  
See application file for complete search history.

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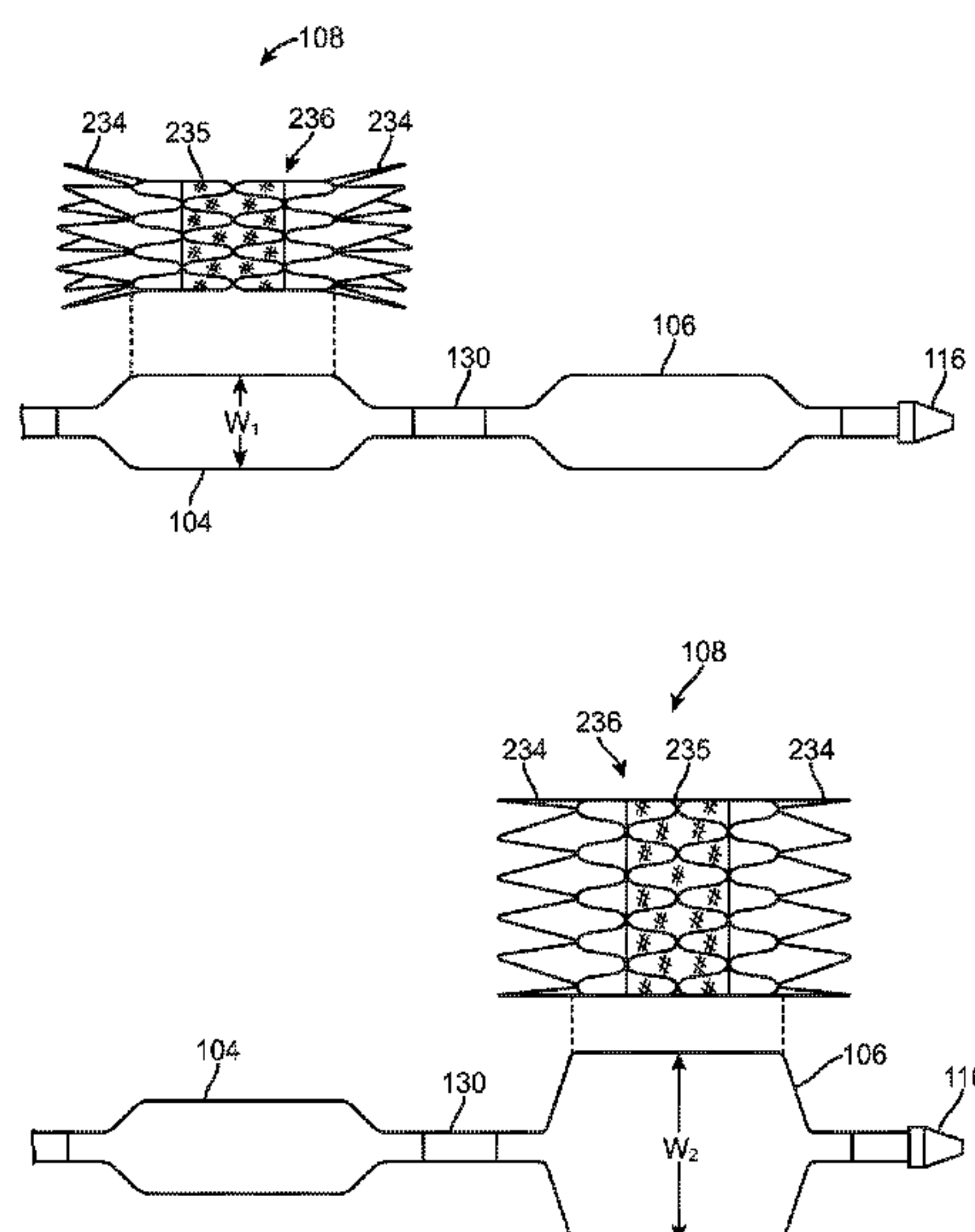
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(57) **ABSTRACT**

A prosthetic valve delivery system for percutaneously delivering and deploying a prosthetic valve within an existing valve is disclosed. The delivery system includes a stented prosthetic valve having a balloon-expandable stent portion with a prosthetic valve disposed therein and at least one self-expanding stent portion. The delivery system further includes a dual balloon catheter having a first balloon on which the stented prosthetic valve is disposed during delivery and a second balloon. Upon delivery within the existing valve, the self-expanding stent portion contacts the existing valve and the first balloon expands the balloon-expandable stent portion to a first diameter such that the stented prosthetic valve is in a first stage deployment configuration. The second balloon then expands the balloon-expandable stent portion to a second diameter, greater than the first diameter, such that the stented prosthetic valve is in a second stage deployment configuration being fully deployed within the existing valve.

**14 Claims, 8 Drawing Sheets**



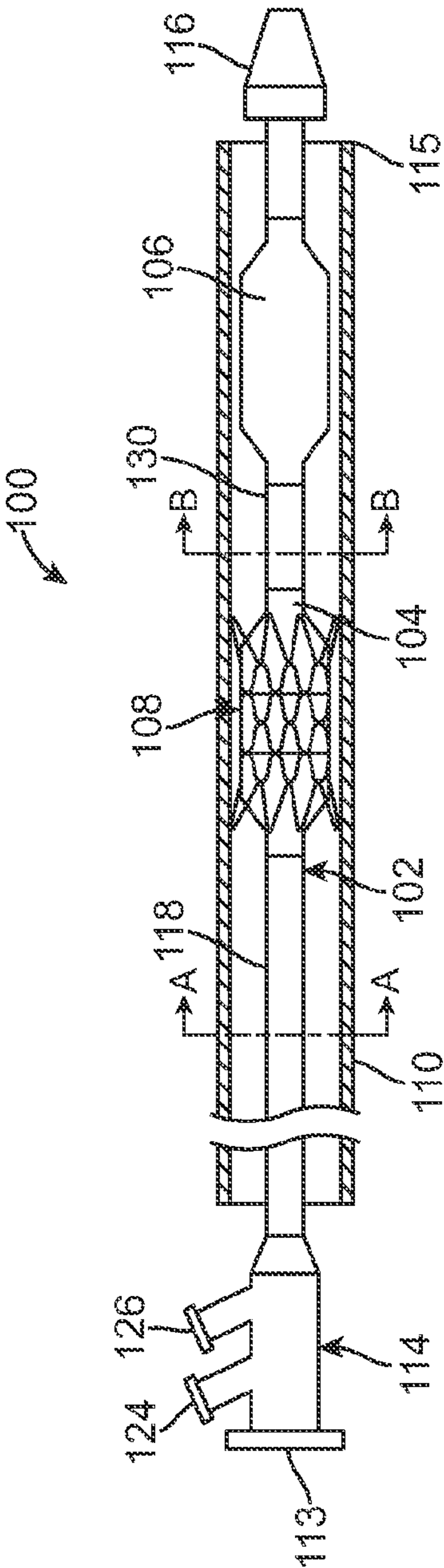


FIG. 1



FIG. 1A

FIG. 1B

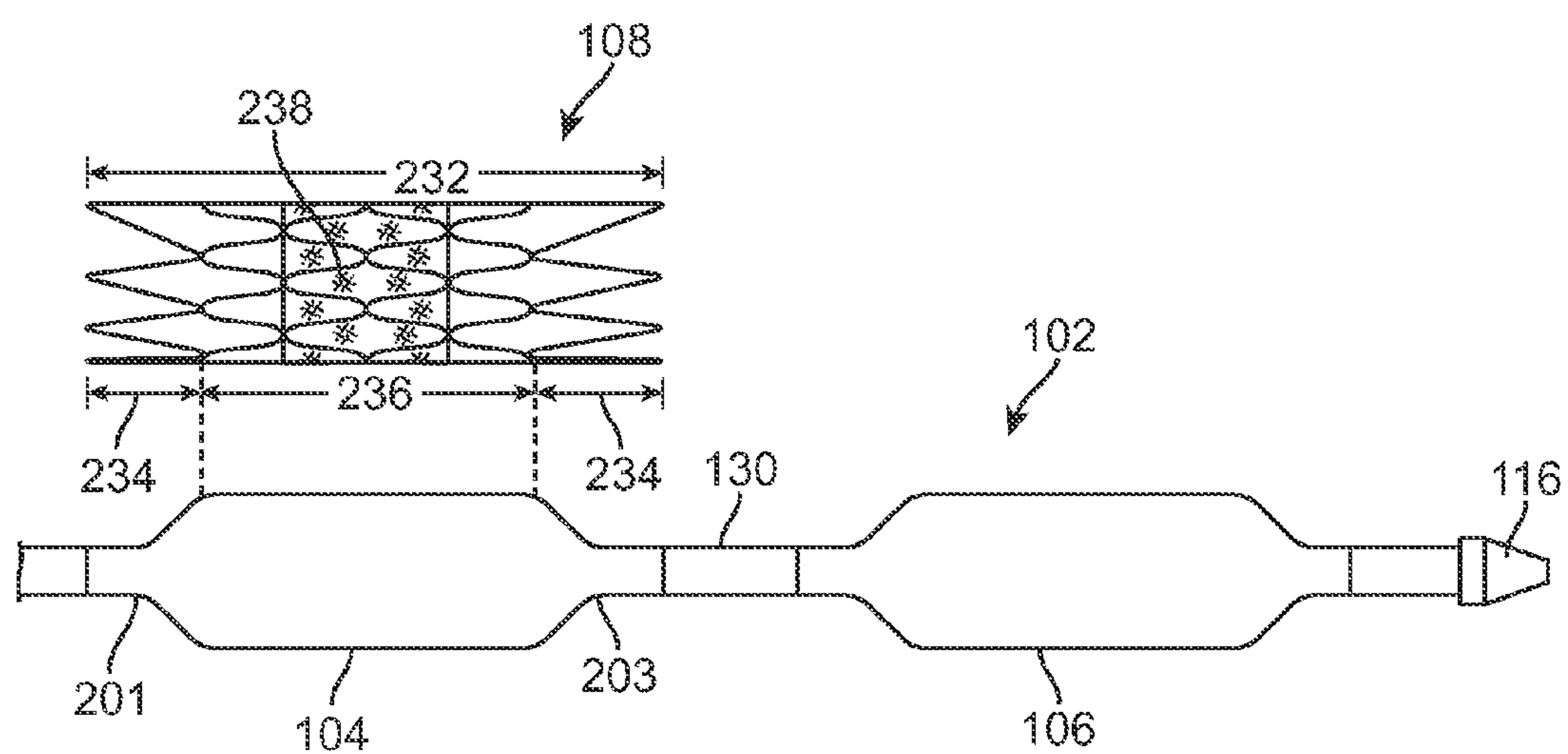


FIG. 2

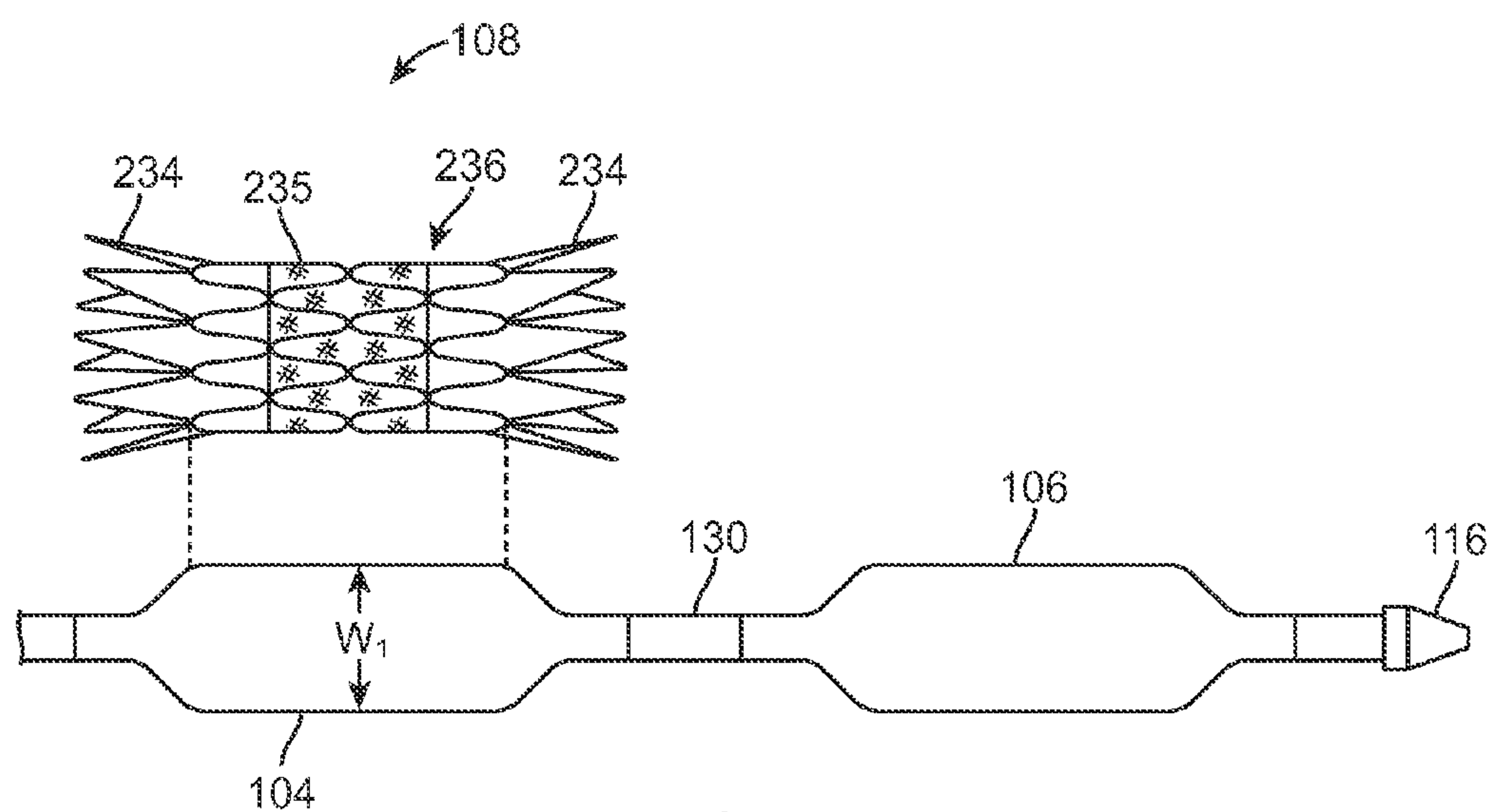


FIG. 3

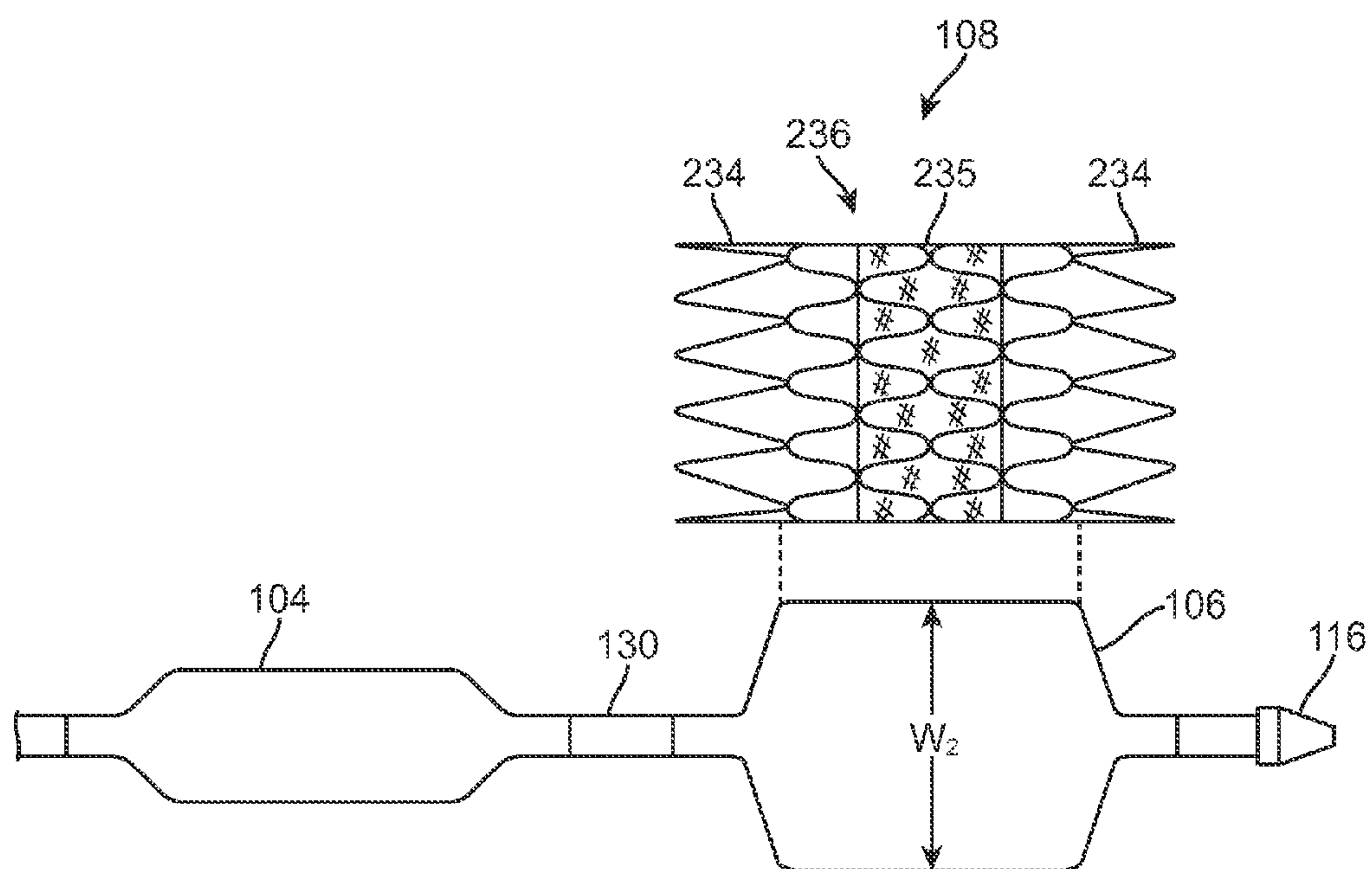


FIG. 4



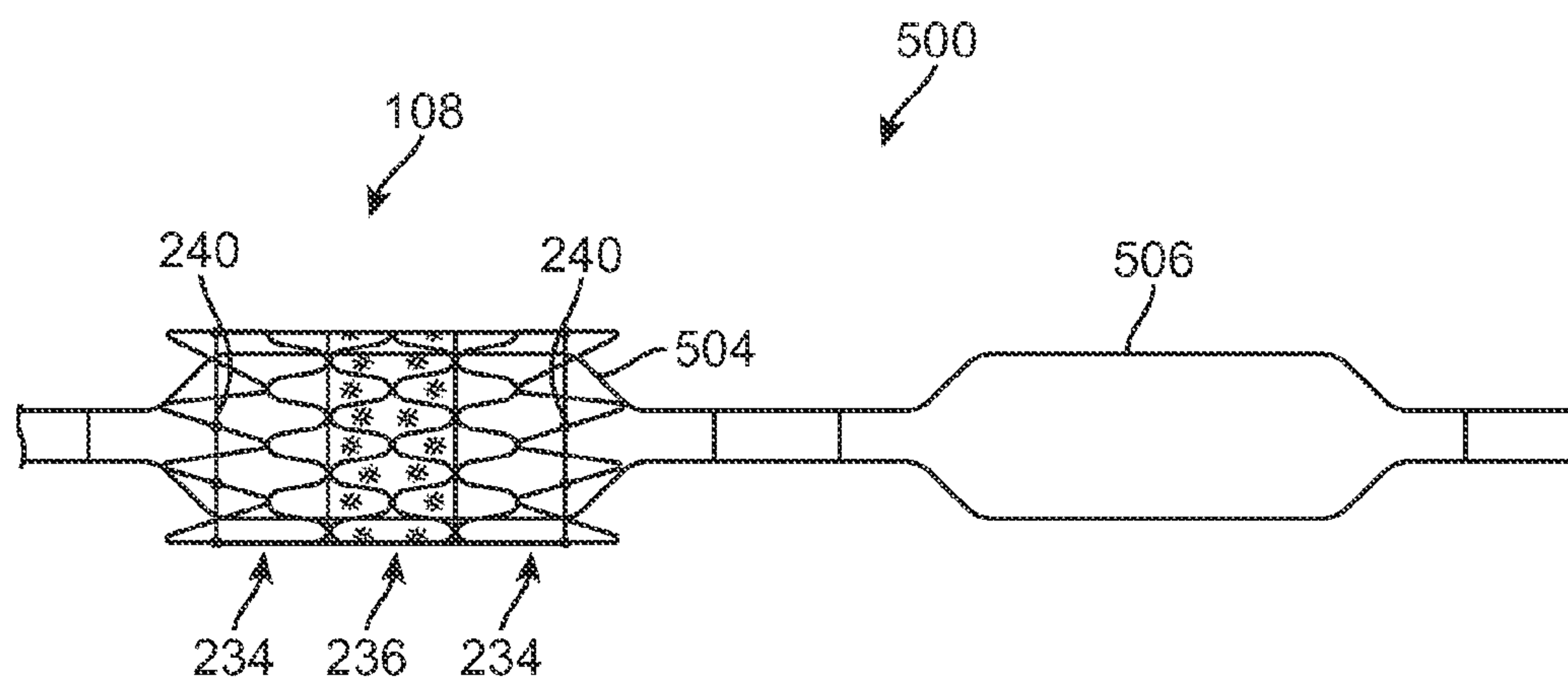


FIG. 5

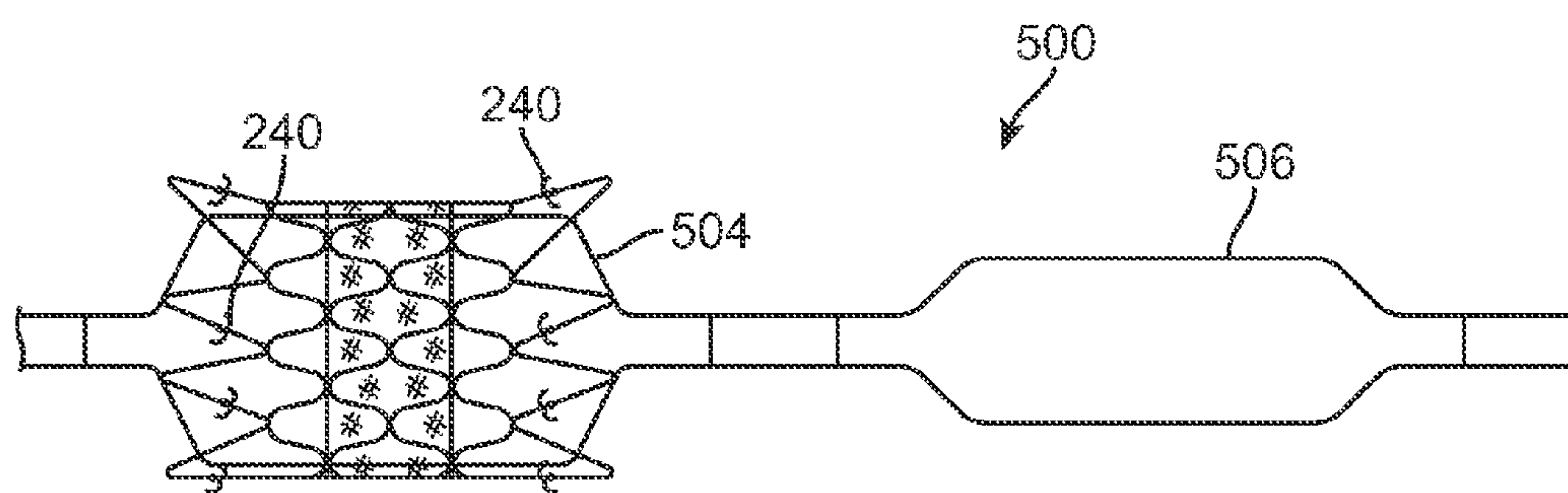


FIG. 5A

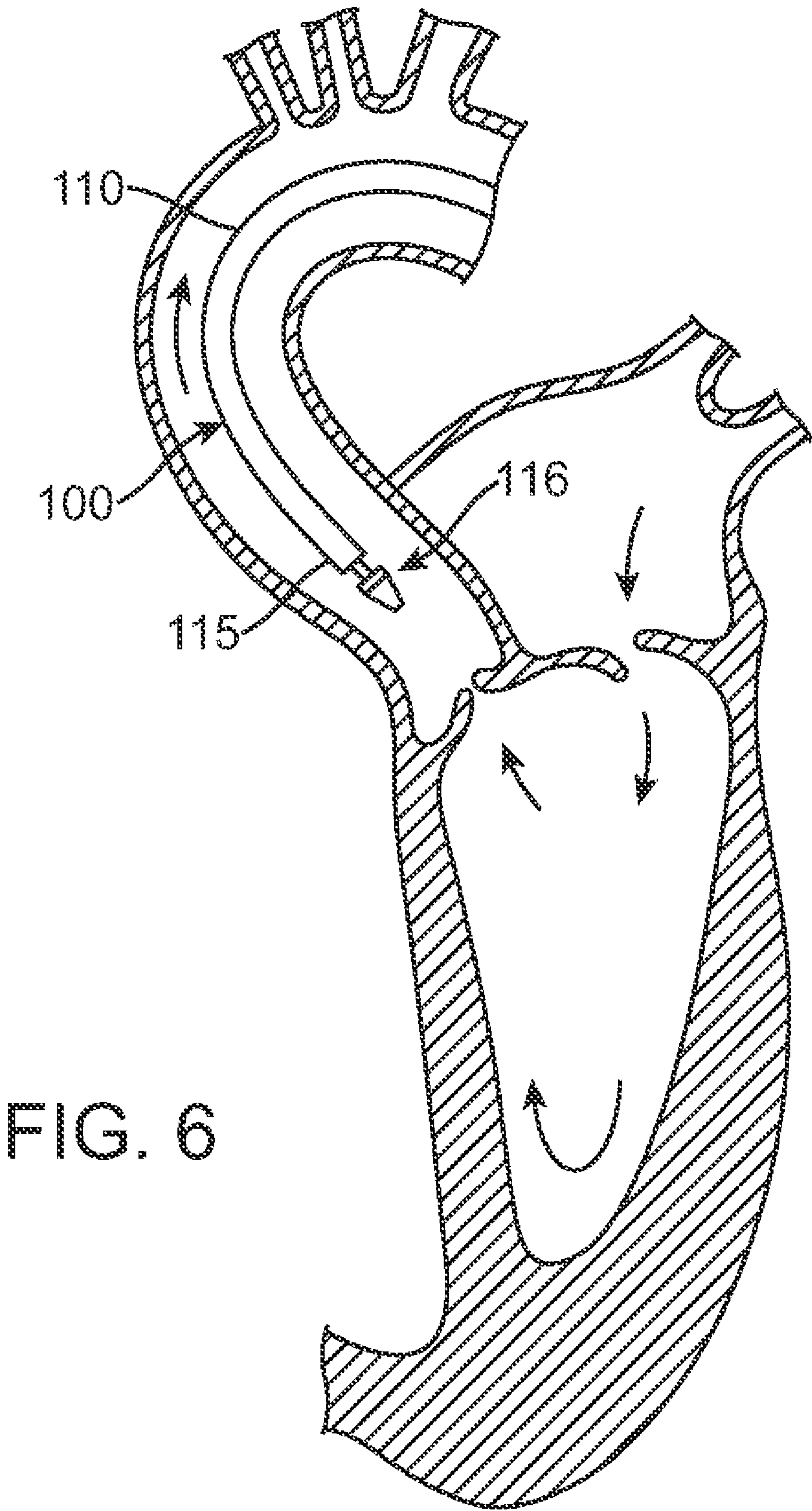


FIG. 6



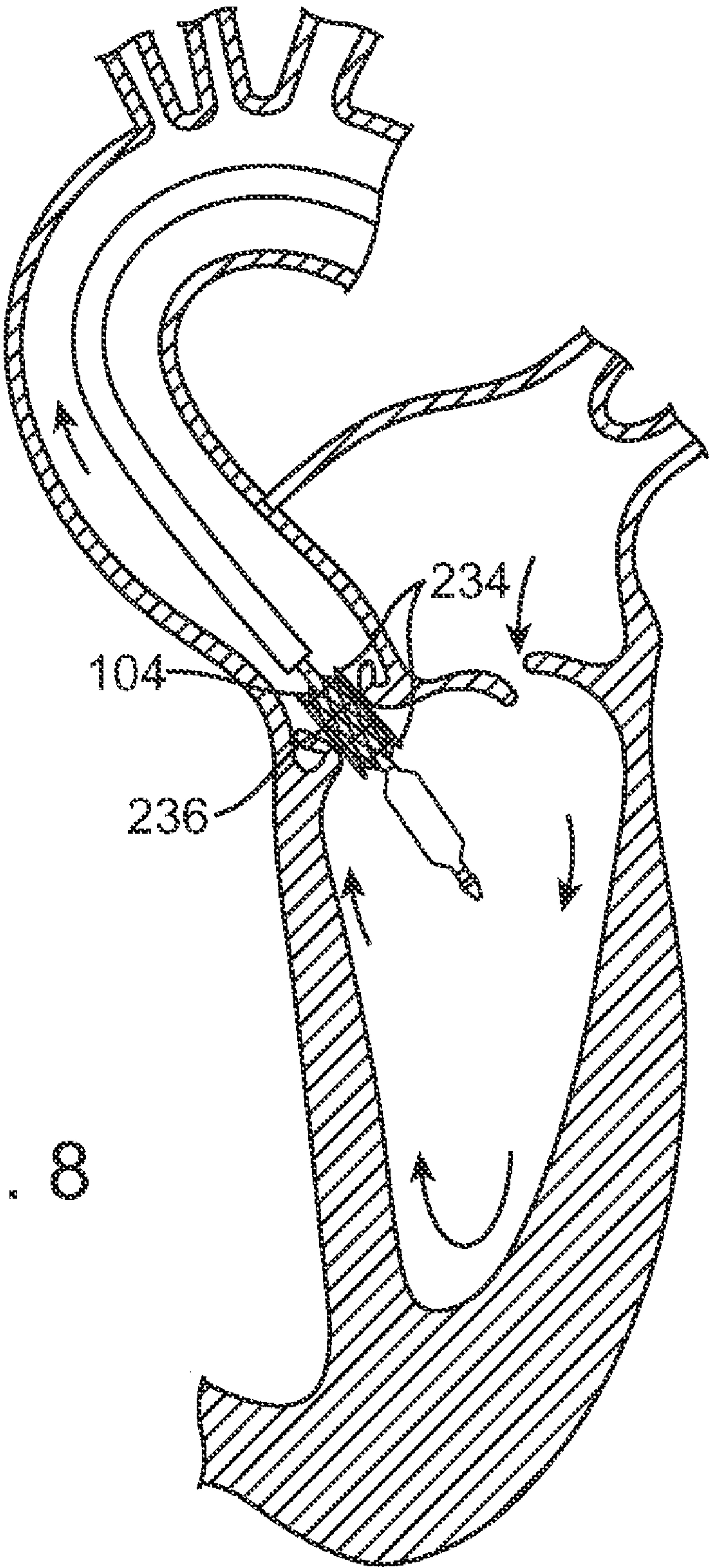


FIG. 8



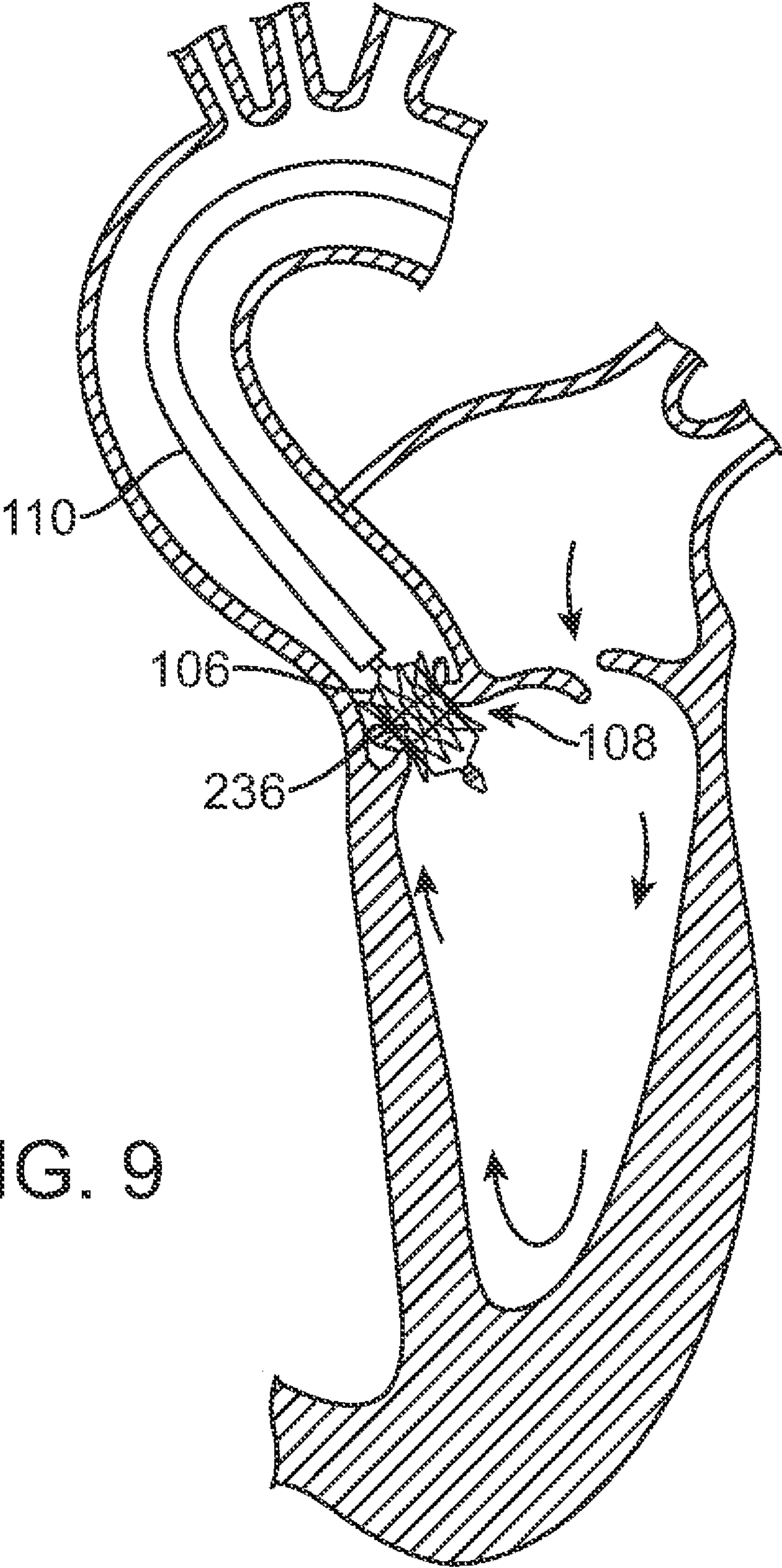


FIG. 9



**PROSTHETIC VALVE DELIVERY SYSTEM****RELATED APPLICATIONS**

This application is a Division of and claims the benefit of U.S. patent application Ser. No. 12/403,114 filed Mar. 12, 2009 now U.S. Pat. No. 8,021,420. The disclosures of which are herein incorporated by reference in their entirety.

**FIELD OF THE INVENTION**

The invention relates generally to delivery systems for deploying a prosthetic heart valve in a non-coronary bypass procedure. More particularly, the invention relates to a catheter-based delivery system for deploying a prosthetic tissue valve having a stent framework with both balloon-expandable and self-expanding stent portions.

**BACKGROUND OF THE INVENTION**

A wide range of medical treatments are known that utilize “endoluminal prostheses.” As used herein, endoluminal prostheses are intended to mean medical devices that are adapted for temporary or permanent implantation within a body lumen, including both naturally occurring and artificially made lumens. Examples of lumens in which endoluminal prostheses may be implanted include, without limitation: arteries, such as those located within the arteries, veins gastrointestinal tract, biliary tract, urethra, trachea, hepatic and cerebral shunts, and fallopian tubes.

Stent prostheses are known for implantation within a body lumen for providing artificial radial support to the wall tissue that defines the body lumen. To provide radial support to a blood vessel, such as one that has been widened by a percutaneous transluminal coronary angioplasty, commonly referred to as “angioplasty,” “PTA” or “PTCA”, a stent may be implanted in conjunction with the procedure. Under this procedure, the stent may be collapsed to an insertion diameter and inserted into the vasculature at a site remote from the diseased vessel. The stent may then be delivered to the desired treatment site within the affected vessel and deployed, by self-expansion or radial expansion, to its desired diameter for treatment.

Recently, flexible prosthetic valves supported by stent structures that can be delivered percutaneously using a catheter-based delivery system have been developed for heart and venous valve replacement. These prosthetic valves may include either self-expanding or balloon-expandable stent structures with valve leaflets attached to the interior of the stent structure. The prosthetic valve can be reduced in diameter, by crimping onto a balloon catheter or by being contained within a sheath component of a delivery catheter, and advanced through the venous or arterial vasculature. Once the prosthetic valve is positioned at the treatment site, for instance within an incompetent native valve, the stent structure may be expanded to hold the prosthetic valve firmly in place. One embodiment of a stented prosthetic valve is disclosed in U.S. Pat. No. 5,957,949 to Leonhardt et al. entitled “Percutaneous Placement Valve Stent”, which is incorporated by reference herein in its entirety.

Due to the size of replacement heart valves, percutaneous delivery of a prosthetic heart valve necessitates a low profile delivery system in order to access the heart via the vasculature without performing a more invasive procedure. Some current delivery systems for delivering and deploying balloon-expandable prosthetic heart valves, for instance, are as large as 24 F, which is too large for femoral access in many patients,

especially in female and pediatric subjects. Such delivery systems often include a large diameter balloon for expanding and deploying the balloon-expandable prosthetic heart valve, which undesirably adds significant bulk to the crossing profile of the delivery system.

When a prosthetic valve is deployed at the treatment site, a fundamental concern is that the prosthesis be deployed as precisely as possible, particularly where the prosthetic valve is used to replace an insufficient or incompetent heart valve. However, accurate positioning of the prosthetic valve may be difficult due to complexities in the anatomy as well as other factors, and an initial deployment of the prosthetic valve may result in a less than optimal positioning or, even worse, an inoperable positioning. As such it would be desirable that the prosthetic valve delivery system accommodate some re-positioning of the prosthetic valve prior to final deployment without adding to the crossing profile of the system.

Another concern when percutaneously delivering a prosthetic valve to replace a heart valve is whether deployment of the replacement heart valve can be accomplished without, or with minimal, blood stoppage during the interventional procedure. Minimizing or eliminating blood stoppage during an interventional procedure is desirable as it avoids complications associated with stopping the heart during the procedure.

Therefore, it would be desirable to have a low profile prosthetic valve delivery system that allows re-positioning of the prosthetic valve, if necessary, and that minimizes or eliminates blood flow stoppage during the valve replacement procedure.

**BRIEF SUMMARY OF THE INVENTION**

Embodiments hereof are directed to a low profile prosthetic valve delivery system for percutaneously delivering and deploying a prosthetic valve within a native or existing valve. The prosthetic valve delivery system includes a stented prosthetic valve having a balloon-expandable stent portion attached at an end to at least one self-expanding stent portion and having a prosthetic valve component disposed within and secured to the balloon-expandable stent portion. The prosthetic valve delivery system further includes a dual balloon catheter having a first balloon on which the stented prosthetic valve is disposed in a delivery configuration and a second balloon, wherein the first balloon has a first working diameter and the second balloon has a second working diameter that is greater than the first working diameter.

Upon delivery of the stented prosthetic valve within an existing valve, the self-expanding stent portion expands into contact with the existing valve and the first balloon expands the balloon-expandable stent portion to a first diameter such that the stented prosthetic valve is in a first stage deployment configuration. The second balloon is then manipulated to be disposed within the stented prosthetic valve in the first stage deployment configuration to expand the balloon-expandable stent portion to a second diameter greater than the first diameter such that the stented prosthetic valve is in a second stage deployment configuration. In the first stage deployment configuration an outer surface of the balloon-expandable stent portion is spaced from the existing valve, whereas in the second stage deployment configuration the outer surface of the balloon-expandable stent portion is in apposition with the existing valve. In an embodiment hereof, the first balloon is disposed on the dual balloon catheter proximal of the second balloon. In another embodiment hereof, the first balloon is disposed on the dual balloon catheter distal of the second balloon.



The prosthetic valve delivery system may further include an outer tubular sheath for radially constraining the self-expanding stent portion(s) of the stented prosthetic valve in the delivery configuration such that when the outer tubular sheath is proximally retracted relative to the self-expanding stent portion(s), the self-expanding stent portion(s) are released to deploy into an expanded configuration.

#### BRIEF DESCRIPTION OF DRAWINGS

The foregoing and other features and advantages of the invention will be apparent from the following description of embodiments thereof as illustrated in the accompanying drawings. The accompanying drawings, which are incorporated herein and form a part of the specification, further serve to explain the principles of the invention and to enable a person skilled in the pertinent art to make and use the invention. The drawings are not to scale.

FIG. 1 is a side view in partial section of a prosthetic valve delivery system in a delivery configuration in accordance with an embodiment hereof.

FIG. 1A is a cross-sectional view of the prosthetic valve delivery system of FIG. 1 taken along line A-A.

FIG. 1B is a cross-sectional view of the prosthetic valve delivery system of FIG. 1 taken along line B-B.

FIG. 2 is a side view of a distal portion of the prosthetic valve delivery system of FIG. 1 showing positioning of a stented prosthetic valve on a first balloon in the delivery configuration.

FIG. 3 is the distal portion of the prosthetic valve delivery system of FIG. 2 showing the stented prosthetic valve in a first stage deployment configuration with the first balloon expanded.

FIG. 4 is the distal portion of the prosthetic valve delivery system of FIG. 2 showing the stented prosthetic valve in a second stage deployment configuration with a second balloon expanded.

FIG. 5 is a side view of a distal portion of a prosthetic valve delivery system in accordance with another embodiment hereof showing positioning of a stented prosthetic valve on a first balloon in the delivery configuration.

FIG. 5A is the distal portion of the prosthetic valve delivery system of FIG. 5 showing the stented prosthetic valve in a first stage deployment configuration with the first balloon expanded.

FIGS. 6-9 illustrate a method of using prosthetic valve delivery system 100 in a heart valve replacement procedure in accordance with an embodiment hereof.

#### DETAILED DESCRIPTION OF THE INVENTION

Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms “distal” and “proximal” are used in the following description with respect to a position or direction relative to the treating clinician. “Distal” or “distally” are a position distant from or in a direction away from the clinician. “Proximal” and “proximally” are a position near or in a direction toward the clinician. However, when discussing positions of the delivery system and/or the prosthetic valve within the aorta proximate the heart, the terms “distal” and “proximal” are used in the following description with respect to the heart. More particularly, “distal” or “distally” are a position away from the heart and “proximal” or “proximally” are a position near or closer to the heart.

The following detailed description is merely exemplary in nature and is not intended to limit the invention or the application and uses of the invention. Although the description of the invention is in the context of heart valve replacement, the invention may also be used for valve replacement in other body passageways where it is deemed useful. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

A prosthetic valve delivery system 100 in accordance with an embodiment hereof is shown and described with reference to FIGS. 1, 1A, and 1B. Prosthetic valve delivery system 100 includes a dual balloon catheter 102 having a first, proximal balloon 104 and a second, distal balloon 106, a stented prosthetic valve 108 mounted on proximal balloon 104 and an outer tubular sheath 110 slidably disposed over dual balloon catheter 102 and prosthetic valve 108.

Dual balloon catheter 102 includes a hub 114 positioned outside the patient and a soft distal tip 116 that aids in steering catheter 102 through the vasculature. Dual balloon catheter 102 has an over-the-wire catheter configuration with a guidewire lumen 112 for accommodating a guidewire (not shown) that extends from a proximal guidewire port 113 of hub 114 to distal tip 116. Guidewire lumen 112 has a proximal segment defined by a proximal shaft portion 118, which is coupled to hub 114 at a proximal end thereof and to proximal balloon 104 at a distal end thereof. As shown in cross-section in FIG. 1A, proximal shaft portion 118 is an extruded shaft that also defines a first inflation lumen 120 and a proximal segment of a second inflation lumen 122. First inflation lumen 120 extends between a first inflation fluid port 124 of hub 114 to an interior of proximal balloon 104, whereas second inflation lumen 122 extends between a second inflation fluid port 126 of hub 114 to an interior of distal balloon 106. As shown in cross-section in FIG. 1B, a distal segment of guidewire lumen 112 is defined by a guidewire shaft 128 that is concentrically disposed within a distal shaft portion 130, whereas a distal, annular segment of second inflation lumen 122 is defined between an exterior surface of guidewire shaft 128 and an interior surface of distal shaft portion 130. Each of distal shaft portion 130 and guidewire shaft 128 extends through proximal balloon 104 and is coupled to proximal shaft portion 110 such that each of guidewire lumen 112 and second inflation lumen 122 is a continuous lumen extending between hub 114 and distal tip 116 or distal balloon 106, respectively, as described above. A distal end of distal shaft portion 130 is coupled to distal balloon 106 and a distal portion of guidewire shaft 128 extends through distal balloon 106 to be coupled to distal tip 116. It would be understood by one of skill in the art of catheter construction that guidewire lumen 112, first inflation lumen 120, and second inflation lumen 122 may have alternate constructions and/or be of other shapes/sizes without departing from the scope of the present invention.

Outer tubular sheath 110, proximal shaft portion 118, distal shaft portion 130 and guidewire shaft 128 may be of any suitable flexible polymeric tubing used in catheter construction, such as tubing of polyethylene terephthalate (PET), polypropylene, nylon, polyethylene, polyether block amide (PEBA), fluoropolymers, such as polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), or combinations thereof. Further as would be understood by one of ordinary skill in the art of catheter design, hub 114 provides a luer hub or other type of fitting that may be connected to sources of inflation fluid and may be of another construction or configuration without departing from the scope of the present invention.



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Proximal and distal balloons **104**, **106** are dilatation balloons of a non-distensible, biocompatible material that may be expanded to a non-stretched working size or diameter upon the application of an inflation fluid at a given pressure. Suitable non-distensible biocompatible materials for fabricating proximal and distal balloons **104**, **106** include but are not limited to nylon 12, nylon 10, polyester, and other polymer blends known in the art. As shown in FIGS. **3** and **4**, proximal balloon **104** is formed to have a first working diameter  $W_1$  and distal balloon **106** is formed to have a second working diameter  $W_2$  that is greater than  $W_1$  to effectuate a two-stage deployment of a balloon-expandable stent portion **236** of stented prosthetic valve **108**, which will be described in greater detail below. By mounting balloon-expandable stent portion **236** of stented prosthetic valve **108** on the smaller proximal balloon **104** during delivery, as shown in FIG. **1**, a crossing profile of the overall delivery system **100** may be reduced from a conventional delivery system that utilizes a single, larger diameter balloon for delivery and deployment. In another embodiment, first working diameter  $W_1$  of proximal balloon **104** may be greater than second working diameter  $W_2$  of distal balloon **106** such that balloon-expandable stent portion **236** of stented prosthetic valve **108** is mounted on distal balloon **106** during delivery.

Stented prosthetic valve **108** is constructed to prevent migration and paravalvular leakage when used in a replacement valve procedure. As best shown in FIGS. **2-4**, stented prosthetic valve **108** includes a tubular stent assembly **232** having self-expanding stent portions **234** attached to respective proximal and distal ends of balloon-expandable stent portion **236**, wherein a prosthetic valve **238** is disposed within and secured to balloon-expandable stent portion **236**. When deployed in vivo, self-expanding stent portions **234** provide improved vessel compliance and sealing of stented prosthetic valve **108** while balloon-expandable stent portion **236** provides radial support for prosthetic valve **238**. Self-expanding stent portions **234** may be attached to balloon-expandable stent portion **236** by sutures, welding or other attachment mechanism as would be known to one of ordinary skill in the art of stent construction. In an embodiment hereof where self-expanding stent portions **234** and balloon-expandable stent portion **236** are of dissimilar metals, a method of welding in accordance with U.S. Pat. Appl. Pub. No. 2005/0154447 to Goshgarian, which is incorporated by reference herein in its entirety, may be employed as the attachment mechanism. In another embodiment, a single self-expanding stent portion **234** may be attached to balloon-expandable stent portion **236** on a blood inflow end of stented prosthetic valve **108**.

Prosthetic valve **238** includes valve leaflets that may be of a synthetic material, a xenograft natural tissue and/or a homograft natural tissue and may form a bicuspid, tricuspid, or tubular replacement valve. Synthetic materials suitable for use in embodiments hereof include DACRON® polyester (Invista North America S.A.R.L., Wilmington, Del., U.S.A.), nylon blends, and vacuum deposition nitinol fabricated materials. Natural tissue for replacement valve leaflets may be obtained from, for example, heart valves, aortic roots, aortic walls, aortic leaflets, pericardial tissue, such as pericardial patches, bypass grafts, blood vessels, intestinal submucosal tissue, umbilical tissue and the like from humans or animals. Prosthetic valve **238** may be sutured or otherwise securely attached within balloon-expandable stent portion **236** of stent assembly **232** as would be known to one of ordinary skill in the art of prosthetic tissue valve construction.

Each self-expanding stent portion **234** is a tubular structure that includes a single sinusoidal ring attached at one or more

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peaks to balloon-expandable stent portion **236**. Upon release of self-expanding stent portions **234** at a treatment site, self-expanding stent portions **234** are sized and constructed to expand into contact with a surface of the treatment site and to provide enough radial force to hold stented prosthetic valve **108** in place during the two-stage deployment of balloon-expandable stent portion **236**, as discussed in detail below. In another embodiment, self-expanding stent portions **234** may each include more than one sinusoidal ring and means for securing the sinusoidal rings together. In another embodiment, self-expanding stent portions **234** may include an ePTFE or DACRON® covering. "Self-expanding" as used herein means that self-expanding stent portions **234** have a mechanical memory to return to an expanded or deployed configuration. Mechanical memory may be imparted to the wire or tubular structure that forms self-expanding stent portions **234** by thermal treatment to achieve a spring temper in stainless steel, for example, or to set a shape memory in a susceptible metal alloy, such as nitinol, or a polymer, such as any of the polymers disclosed in U.S. Pat. Appl. Pub. No. 2004/0111111 to Lin, which is incorporated by reference herein in its entirety. In embodiments hereof, self-expanding stent portions **234** may be made from stainless steel, a pseudo-elastic metal such as nitinol, or a so-called super alloy, which may have a base metal of nickel, cobalt, chromium, or other metal.

Balloon-expandable stent portion **236** is a tubular structure having four sinusoidal rings attached peak-to-peak and valley-to-valley. In another embodiment, balloon-expandable stent portion **236** may include fewer or more sinusoidal rings and have longitudinal connectors or other means for attaching the sinusoidal rings together. In various embodiments hereof, balloon-expandable stent portion **236** of stent assembly **232** may be constructed of, for e.g., platinum-iridium, cobalt chromium alloys (MP35N, L605), stainless steel, tantalum or other stent materials.

Some examples of self-expanding and balloon-expandable stents that may be adapted for use as stent portions **234**, **236** in embodiments hereof are shown in U.S. Pat. No. 4,733,665 to Palmaz, U.S. Pat. No. 4,800,882 to Gianturco, U.S. Pat. No. 4,886,062 to Wiktor, U.S. Pat. No. 5,133,732 to Wiktor, U.S. Pat. No. 5,292,331 to Boneau, U.S. Pat. No. 5,421,955 to Lau, U.S. Pat. No. 5,776,161 to Globerman, U.S. Pat. No. 5,935,162 to Dang, U.S. Pat. No. 6,090,127 to Globerman, U.S. Pat. No. 6,113,627 to Jang, U.S. Pat. No. 6,663,661 to Boneau, and U.S. Pat. No. 6,730,116 to Wolinsky et al., each of which is incorporated by reference herein in its entirety.

As illustrated in FIGS. **1** and **2**, when balloon-expandable stent portion **236** with prosthetic valve **108** secured therein is crimped or otherwise collapsed onto proximal balloon **104** in the delivery configuration, self-expanding stent portions **234** extend over respective proximal and distal neck portions **201**, **203** of proximal balloon **104** and are constrained in a contracted or compressed delivery configuration by outer tubular sheath **110**. Once prosthetic valve delivery system **100** is tracked through the vasculature and positioned for treatment as discussed further below, outer tubular sheath **110** may be retracted to thereby release self-expanding stents **234** of stented valve prosthesis **108** so that they assume their expanded configuration (shown in FIG. **3**) and contact a surface of the treatment site. An inflation fluid may then be introduced into proximal balloon **104** via first inflation fluid port **124** and first inflation lumen **120** to inflate proximal balloon **104** to working diameter  $W_1$  and thereby expand balloon-expandable stent portion **236** to a first outer diameter in which stented valve prosthesis **108** is in an initial or first stage deployment configuration as shown in FIG. **3**. Working



diameter  $W_1$  of proximal balloon **104** is sized to be less than a diameter of the body lumen in which stented prosthetic valve **108** is to be placed such that an exterior surface **235** of balloon-expandable stent portion **236** is spaced from the surface of the body lumen/treatment site to permit blood flow to continue during the first stage expansion of stented prosthetic valve **108**. Proximal balloon **104** may then be deflated and proximally retracted leaving stented prosthetic valve **108** in its first stage deployment configuration to be held at the treatment site by the radial force provided by self-expanding stent portions **234**. Distal balloon **106** may then be proximally retracted to be disposed within balloon-expandable stent portion **236** and an inflation fluid introduced into distal balloon **106** via second inflation fluid port **126** and second inflation lumen **122**. Distal balloon **106** is then expanded to working diameter  $W_2$  thereby radially expanding balloon-expandable stent portion **236** to a larger, second outer diameter in which stented valve prosthesis **108** is in a second stage deployment configuration as shown in FIG. 4, whereby prosthetic valve **238** is fully expanded. Working diameter  $W_2$  of distal balloon **106** is sized to be approximately equal to a diameter of the body lumen in which stented prosthetic valve **108** is to be placed such that exterior surface **235** of balloon-expandable stent portion **236** makes contact with the surface of the treatment site to be in apposition therewith.

The three phase deployment of stented prosthetic valve **108** permits a clinician to visualize under fluoroscopy the position of stented prosthetic valve **108** after deployment of self-expanding stent portions **234** and/or after first stage deployment of balloon-expandable stent portion **236**. Such visualization may be used to confirm proper positioning of stented prosthetic valve **108** prior to second stage deployment of balloon-expandable stent portion **236**, i.e., prior to full deployment of stented prosthetic valve **108**. If improper positioning is identified, stented prosthetic valve **108** may be re-positioned by engagement with proximal balloon **104** at working diameter  $W_1$ . In an embodiment where stented prosthetic valve **108** is to be used to replace an incompetent aortic valve, such as described below with reference to FIGS. 5-8, visualizing the initial deployment positioning of the stented prosthetic valve can be used to assure that the coronary arteries will not be blocked prior to final deployment of the stented prosthetic valve.

In another embodiment, dual balloon catheter **102** may be modified to include a single inflation lumen in fluid communication with both proximal and distal balloons **104**, **106**. Proximal balloon **104** may be constructed to fully expand to working diameter  $W_1$  and distal balloon **106** may be constructed to fully expand to working diameter  $W_2$ , wherein in one embodiment  $W_1$  is about half the size of  $W_2$ . During preliminary inflation of proximal balloon **104** with inflation fluid, distal balloon **106** does not substantially expand. After proximal balloon **104** has been used to expand stented prosthetic valve **108** into a first stage deployment configuration a vacuum may be pulled to deflate proximal balloon **104**, as well as to remove any inflation fluid that may reside within distal balloon **106** so that distal balloon **106** may be proximally retracted and disposed within stented prosthetic valve **108**. A second stage expansion of stented prosthetic valve **108** is then performed by introducing inflation fluid sufficient to expand distal balloon **106** and thereby expand stented prosthetic valve **108** into a second stage deployment configuration, i.e., full deployment. In another embodiment where dual balloon catheter **102** may be modified to include a single inflation lumen, proximal balloon **104** may be of a construction and a material that will fully expand to working diameter  $W_1$  at 1 or 2 ATM, whereas distal balloon **106** may be of a

construction and another material that will fully expand to working diameter  $W_2$  at 3 ATM or greater.

In another embodiment, stent delivery system **100** may be modified to be of a rapid exchange (RX) catheter configuration without departing from the scope of the present invention such that guidewire lumen **112** only extends within a distal portion of catheter **102**. In such an embodiment, proximal shaft portion **118** may include a metal hypotube with a guidewire transition area having a proximal guidewire port being positioned proximal of proximal balloon **104**.

FIGS. 5 and 5A illustrate a side view of a distal portion of a prosthetic valve delivery system **500** having first and second balloons **504**, **506** in accordance with another embodiment hereof. In contrast to prosthetic valve delivery system **100** which includes outer tubular sheath **110** for constraining self-expanding stent portions **234** of stented prosthetic valve **108** in a delivery configuration, prosthetic valve delivery system **500** utilizes frangible bands or ties **240** to constrain self-expanding stent portions **234** during delivery through the vasculature, as shown in FIG. 5. In such an embodiment, stented prosthetic valve **108** may be positioned on a longer, first balloon **504** of dual balloon catheter **502** with both balloon-expandable stent portion **236** and self-expanding stent portions **234** disposed around a working diameter  $W_1$  of first balloon **504** during delivery and initial expansion. Frangible bands **240** temporarily hold self-expanding stent portions **234** in the collapsed, delivery configuration and are torn or broken upon or shortly after initial expansion of first balloon **504**. As such, self-expanding stent portions **234** are released to expand into contact with the treatment site as first balloon **504** is expanded to its working diameter, which also expands balloon-expandable stent portion **236** to a first stage deployment configuration, as shown in FIG. 5A. Any feature and/or operation not described with reference to delivery system **500** can be considered similar or identical to those described with reference to delivery system **100**.

FIGS. 6-9 illustrate a method of using prosthetic valve delivery system **100** in accordance with an embodiment hereof to perform a heart valve replacement procedure, more particularly an aortic valve replacement, with minimal blood flow stoppage or interruption. Blood flow is represented by the arrows shown in each of the figures. With reference to FIG. 6, prosthetic valve delivery system **100** is shown after having been introduced into the vasculature via a percutaneous puncture, a.k.a the Seldinger technique, and having been tracked through the vasculature, over the aortic arch and into the descending aorta so that distal tip **116** is positioned proximate the aortic valve. Prosthetic valve delivery system **100** is then proximally advanced toward the heart until distal end **115** of outer tubular sheath **110** is positioned within the left ventricle such that delivery system **100** bridges the aortic valve with proximal balloon **104** and stented valve prosthesis **108** substantially concentrically positioned within the native aortic valve. Outer tubular sheath **110** is then retracted relative to dual balloon catheter **102**, thereby leaving distal balloon **106** within the left ventricle, as shown in FIG. 7; however, blood flow is uninterrupted during this step of the method. Continued retraction of outer tubular sheath **110** releases self-expanding stent portions **234** of stented valve prosthesis **108** so that they provide a radial force to displace the native aortic valve leaflets and hold a concentric position of stented valve prosthesis **108** within the aortic root. Proximal balloon **104** may then be expanded to first working diameter  $W_1$  to expand balloon-expandable portion **236** into the first stage deployment configuration shown in FIG. 8, wherein an outer surface of balloon-expandable stent portion **236** does not contact the native aortic valve. Further since first working



diameter  $W_1$  is sized to be less than the diameter of the native aortic valve, expansion of proximal balloon **104** to first working diameter  $W_1$  does not block blood flow through the aortic valve, viz., the heart, during this step of the procedure. In an embodiment, first working diameter  $W_1$  is sized to expand balloon-expandable stent portion **236** only enough to detach the balloon-expandable stent portion from proximal balloon **104**. A preliminary position of stented prosthetic valve **108** may be checked via fluoroscopy to determine whether any re-positioning of the prosthetic valve is needed prior to deflating proximal balloon **104**. If re-positioning is needed, stented prosthetic valve **108** is held in place only by self-expanding stent portions **234** with balloon-expandable stent portion **236** still attached to dual balloon catheter **102**, i.e., in contact with inflated proximal balloon **104**, such that adjustments to the position of stented prosthetic valve **108** can be made by pulling or pushing catheter **102**.

Once proximal balloon **104** is deflated, dual balloon catheter **102** is retracted within outer tubular sheath **110** until distal balloon **106** is concentrically disposed within stented prosthetic valve **108**, and, more particularly, positioned within balloon-expandable stent portion **236**. Distal balloon **106** may then be expanded to second working diameter  $W_2$  to expand balloon-expandable portion **236** into the second or final stage deployment configuration shown in FIG. 9, wherein the outer surface of balloon-expandable stent portion **236** contacts the native aortic valve to be in apposition therewith. In some instances, during the step of positioning the second or distal balloon **106** within stented prosthetic valve **108**, self-expanding stent portions **234** may not be sufficient to hold the prosthesis in position within the aortic valve with the heart beating normally, such that rapid pacing of the ventricles, i.e., inducing ventricle hyperactivity, may be necessary to inhibit the flow of blood through stented prosthetic valve **108** until distal balloon **106** has been inflated therein. In other instances, stopping blood flow may be necessary if the process of inflating the second or distal balloon **106** causes the pressure on the adjacent mitral valve to become too high. In this case, it may become necessary to again inhibit the function of the left ventricle by rapidly pacing the heart to prevent contractile displacement of the ventricle chamber. Distal balloon **106** is then deflated and prosthetic valve delivery system **100** is removed from the vasculature leaving stented prosthetic valve **108** deployed within the native aortic valve. Stented prosthetic valve **108** is constructed to prevent migration of the prosthesis and to avoid paravalvular leakage when used in a heart valve replacement procedure. When deployed within the native aortic valve as shown in FIG. 9, self-expanding stent portions **234** of stented prosthetic valve **108** provide improved compliance and sealing against the displaced aortic valve leaflets and/or the aortic root while balloon-expandable stent portion **236** provides radial support for prosthetic valve **238**.

While various embodiments according to the present invention have been described above, it should be understood that they have been presented by way of illustration and example only, and not limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the invention. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the appended claims and their equivalents. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, can be used in combination with the features of

any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

What is claimed is:

1. A method of percutaneously delivering and deploying a prosthetic valve within an existing valve comprising:
  - tracking a prosthetic valve delivery system through the vasculature to the existing valve, wherein the prosthetic valve delivery system includes
    - a stented prosthetic valve having a balloon-expandable stent portion with a prosthetic valve component disposed therein and attached at each end to a respective self-expanding stent portion, and
    - a dual balloon catheter having a first balloon with a first working diameter around which the stented prosthetic valve is disposed during delivery and a second balloon having a second working diameter that is greater than the first working diameter;
  - positioning the first balloon with the stented prosthetic valve thereon within the existing valve to be replaced;
  - releasing the self-expanding stent portions of the stented prosthetic valve into contact with the existing valve;
  - expanding the first balloon to the first working diameter to expand the balloon-expandable stent portion of the stented prosthetic valve to a first diameter such that the stented prosthetic valve is in a first stage deployment configuration;
  - manipulating the dual balloon catheter to position the second balloon within the stented prosthetic valve in the first stage deployment configuration; and
  - expanding the second balloon to the second working diameter to expand the balloon-expandable stent portion of the stented prosthetic valve to a second diameter greater than the first diameter such that the stented prosthetic valve is in a second stage deployment configuration.
2. The method of claim 1, wherein in the first stage deployment configuration an outer surface of the balloon-expandable stent portion is spaced from the existing valve.
3. The method of claim 2, wherein in the second stage deployment configuration the outer surface of the balloon-expandable stent portion is in apposition with the existing valve.
4. The method of claim 1, wherein the prosthetic valve delivery system further includes an outer tubular sheath defining a lumen in which the dual balloon catheter is slidably disposed whereby the outer tubular sheath radially constrains the self-expanding stent portions of the stented prosthetic valve during delivery.
5. The method of claim 4, wherein the step of releasing the self-expanding stent portions includes proximally retracting the outer tubular sheath relative to the dual balloon catheter to expose the self-expanding stent portions.
6. The method of claim 1, wherein the first balloon is positioned on the dual balloon catheter proximal of the second balloon.
7. The method of claim 6, wherein the step of manipulating the dual balloon catheter includes deflating the first balloon and proximally retracting the dual balloon catheter to dispose the second balloon within the stented prosthetic valve.
8. The method of claim 1, wherein the first balloon is positioned on the dual balloon catheter distal of the second balloon.
9. The method of claim 8, wherein the step of manipulating the dual balloon catheter includes deflating the first balloon and distally advancing the dual balloon catheter to dispose the second balloon within the stented prosthetic valve.
10. The method of claim 1, wherein the existing valve is a heart valve.

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11. The method of claim 10, wherein during the step of expanding the first balloon blood flow continues through the heart.
12. The method of claim 1, wherein the first working diameter of the first balloon is less than a diameter of the existing valve. 5
13. The method of claim 12, wherein the second working diameter of the second balloon is substantially equal to the diameter of the existing valve.

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14. The method of claim 1 further comprising:  
visualizing the stented prosthetic valve in the first stage deployment configuration to assure proper deployment within the existing valve.

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